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10/811,343

03/26/2004

William A. Cook

3433-492

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7590

02/04/2009

WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP
111 MONUMENT CIRCLE, SUITE 3700
INDIANAPOLIS, IN 46204-5137

EXAMINER

PREBILIC, PAUL B

ART UNIT

PAPER NUMBER

3774

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DELIVERY MODE

02/04/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/811,343 | Applicant(s) COOK ET AL. | |
| | Examiner Paul B. Prebilic | Art Unit 3774 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-54, 64-66 and 68-70 is/are pending in the application.
- 4a) Of the above claim(s) 68-70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-54 and 64-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/3/2008</u> | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 3, 2008 has been entered.

The Applicant failed to point out where there is support from the original specification as requested in the most recent Office action; see the "Conclusion" section of the Office action mailed July 3, 2008. Failure to point out support in the future could result in the response being deemed nonresponsive. Support for the new language of claims 27 and 45 was found on specification page 15, lines 9-23, and support for the new language of claim 64 was found on specification page 5, lines 6-9 and page 16, lines 19-26, respectively.

Similarly, the Applicant failed to identify or at least acknowledge the request for copending applications that set forth similar subject matter; see the "Conclusion" section of the previous Office action.

Election/Restrictions

Newly submitted claims 68-70 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the new claims are drawn to a product not a method as originally claimed. Even though claim 68 is a product-by-process claim, it still would have to be treated as a product claim giving

Art Unit: 3774

weight only to the structure implied by the method of claim 64; see MPEP 2113. The issue is presented with regard to claim 69 that is an independent product claim. Claim 70 is dependent upon withdrawn claim 69 so it is also withdrawn.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 68-70 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Specification

The disclosure is objected to because of the following informalities: the continuity data on page 1 of the specification is not correct because there the parent application was not pending when the present application was filed. Specifically, there appears to be a discontinuity between the present application and the parent application 09/798,441 because no extension of time was filed and granted in the parent application after the September 26, 2003 Office action was mailed. It is noted that a fee for an extension was registered in the parent application but the extension request is not present in the file or is missing; see MPEP 201.06(c) X and 201.11. Therefore, the effective filing date of the present application is considered to be March 26, 2004.

If the applicant show that a paper is missing and the parent application such that copendency is established, then the continuity data will have to be corrected to indicate that the application 09/798,441 is a divisional application not a continuation application

Art Unit: 3774

of application 08/916,490; see the continuing data of the parent application and the amendment filed July 14, 2003 therein.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27-66 are rejected under 35 U.S.C. 102(b) as being anticipated by Cook et al (US 6,206,931). Cook clearly anticipates the present claim language where the disclosure thereof is identical to the present application; see column 6, line 46 et seq.

Claims 27, 28, 31-34, and 45-49 are rejected under 35 U.S.C. 102(b) as being anticipated by McCusker (US 3,649,163). McCusker anticipates the claim language where the attached tunica muscularis is within the radial muscle attached to the submucosa; see column 3, lines 39-65, especially lines 58-65 of column 3 as well as column 3, line 66 to column 4, line 44.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Badylak et al (US 5,695,998) in view of McCusker (US 3,649,163) and O'Leary (US 5,298,222) or Kemp (US 5,460,962). Badylak discloses a submucosal tissue source which is first delaminated into tunica muscularis and tunica mucosa (i.e. submucosal tissue) prior to being disinfected; see column 3, lines 3-44. McCusker teaches that even when separation of the submucosa is made there will remain some tunica muscularis prior to further treatment; see column 3, lines 39-65, particularly, lines 58-65 of column 3. Additionally, present claim language requires a step of separation after the disinfectant treatment rather than before as Badylak discloses. However, O'Leary (see columns 1 and 2, particularly column 1, lines 14-21 where the tissue is treated with an antibiotic (i.e. a disinfectant) prior to further processing) or Kemp (see column 3, lines 21 et seq., particularly column 5, lines 12-24 where a sterilized one inch sample is removed from the one foot tissue source) teaches that it was known to sterilize similar tissues prior to further mechanical processing. Therefore, it is the Examiner's position that it would have been *prima facie* obvious to disinfect the submucosal tissue source of Badylak prior to delamination for the same reason that O'Leary does the same; see column 1, lines 34-39.

With regard to claims 28 and 29, Applicants are directed to see column 1, lines 41-59 of Badylak.

With regard to claim 30, Applicants are directed to see column 8, lines 28-30 of Badylak.

With regard to claim 37, Applicants are directed to see column 7, lines 55-64.

With regard to claims 31-33, Applicants are directed to see Table 1 on column 8 where hydrogen peroxide is the oxidizing agent or peroxy compound. Acetyl peroxide is the organic peroxy compound of claim 33.

With regard to claim 42 and 43, the solutions set forth in Example 2 of Badylak should inherently have the same pH as the claimed solution because they are the same as the claimed solutions. Alternatively, the Examiner asserts that the pH is Badylak is within the claimed range; see MPEP 2112 which is incorporated herein by reference.

With regard to claim 46, the Applicants are directed to see column 8, lines 28-30 of Badylak.

With regard to claims 48, 49, and 51, the Applicants are directed to see Table 1 on column 8 where hydrogen peroxide is the oxidizing agent or peroxy compound as claimed. Acetyl peroxide is the organic peroxy compound of claim 51.

Claims 64-66 are rejected under 35 U.S.C. 103(a) as obvious over Badylak et al (US 5,695,998) or Abraham et al (US 5,993,844) in view of Badylak (US 5,554,389) and O'Leary (US 5,298,222) or Kemp (US 5,460,962) where Hodde et al (NPL) is cited as extrinsic evidence that glycosaminoglycan is present in small intestine submucosa. Badylak discloses a submucosal tissue source which is first delaminated into tunica muscularis and tunica mucosa (i.e. submucosal tissue) prior to being disinfected; see column 3, lines 3-44. Similarly, Abraham discloses providing a submucosal tissue source that is treated with a disinfecting agent and separated from the submucosal layer; see Example 1, column 4, line 49 to column 5, line 6, and column 8, line 55 to column 9, line 13. The claimed properties of the "wherein" clauses, in claim 64, are

Art Unit: 3774

considered inherent to Badylak or Abraham because the tissue is treated in a manner identical to the claimed invention. Abraham discloses that the resulting tissue is sterile and endotoxin free; see column 5, lines 2-6. Since the sterilization step can be performed before or after the separation step, the claimed method is fully disclosed by either Badylak or Abraham.

Abraham or Badylak do not disclose the use of urinary tract tissue as the tissue source as claimed. However, Badylak ('389) teaches that the same was known to the art; see the abstract. For this reason, the Examiner asserts that it would have been *prima facie* obvious to an ordinary artisan to utilize urinary tract tissue as the tissue source for the same reasons that Badylak ('389) utilizes the same.

If one interprets the present claim language as requiring a step of separation after the disinfectant treatment rather than before as Badylak or Abraham discloses, then the Badylak or Abraham do not fully disclosed the claimed method. However, O'Leary (see columns 1 and 2, particularly column 1, lines 14-21 where the tissue is treated with an antibiotic (i.e. a disinfectant) prior to further processing) or Kemp (see column 3, lines 21 et seq., particularly column 5, lines 12-24 where a sterilized one inch sample is removed from the one foot tissue source) teaches that it was known to sterilize similar tissues prior to further mechanical processing. Therefore, it is the Examiner's position that it would have been *prima facie* obvious to disinfect the submucosal tissue source of Badylak or Abraham prior to delamination for the same reason that O'Leary does the same; see column 1, lines 34-39.

With regard to the new limitation that the matrix contain or retain four materials found therein naturally. Hodde et al teaches that small intestine submucosa retains glycosaminoglycans; see the abstract thereof. Therefore, the examiner asserts that small intestine submucosa inherently retains the other components as well since there are naturally present in submucosa material and are not necessarily removed by the treatment steps set forth by Badylak or Abraham.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

Art Unit: 3774

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Paul Prebilic/
Paul Prebilic
Primary Examiner
Art Unit 3774